

AM100802

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 10/626,943 Confirmation No. : 3231  
Applicants : Rubino, *et al.*  
Filed : July 25, 2003  
Art Unit : 1611  
Examiner : Greg Polansky  
Customer No. : 38199  
Title : PARENTERAL FORMULATIONS

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants submit to the Examiner the attached document listing and this paper pursuant to 37 CFR § 1.56 and § 1.97-1.98.

Pursuant to 37 CFR 1.97(e)(1), each item of information contained in this information disclosure statement was first cited in a communication from the Japanese patent office in a counterpart Japanese application not more than three months prior to the filing of this information disclosure statement. Therefore, no fees are believed due.

**REMARKS**

Listed in the attached document listing are documents listed in a Japanese Official Action received March 11, 2008 in counterpart Japanese Patent Application No. 2004-524806 (the "Action"). A translated copy of the Action is enclosed herewith.

A copy of the US Patent corresponding to document identified in the Action as cited reference 5 was previously provided in the Information Disclosure Statement filed November 21, 2003 as document "CC."

Japanese Patent Application No. JP-A-9-512018 corresponds to English-language International Publication No. WO 95/28406 supplied herewith as document "QQ." WO 02/040000 is supplied herewith as document "RR." HIDALGO ET AL, "The Rapamycin-Sensitive Signal Transduction Pathway as a Target for Cancer Therapy", Oncogene, Vol. 19, No. 56, pp. 6680-6686, (December 2000) is submitted herewith as document "UU." Japanese Patent Application No. JP-A-7-505628 corresponds to English-language International Publication No. WO 93/19763 supplied herewith as document "SS."

The dates of items VV and WW are sufficiently early that the month of publication is not in issue. Injection - the basis, preparation and application - , Nanzando Edition 1, pages 21-23 (1995) is supplied herewith as document "VV." Pharmaceutical Additive Dictionary, Yakuji Nippou Limited, pages 2-3, 6, 38-39, 63, 90-91, 117, 214, (1994) is supplied herewith as document "WW." This document refers generally to excipients which can be included in injectable formulations including, for example, ascorbic acid, aminoacetic acid, citric acid, dibutylhydroxytoluene, d- $\delta$ -tocopherol, propyl gallate and butylphthalyl butylglycolate.

Japanese Patent Application No. JP-A-10-509699 corresponds to English-language International Publication No. WO 96/13273 supplied herewith as document "TT."

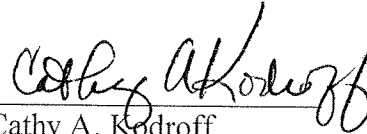
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Supplemental IDS  
June 11, 2008  
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The Examiner is respectfully requested to consider the enclosed document identified in this paper and in the attached document listing during the course of examination of this application.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to our Deposit Account, Number 08-3040.

Respectfully submitted,

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